

U.S.S.N. 08/359,937
Filed: December 20, 1994
Amendment

Q1
cancel
composition have a diameter of between 0.1 μm and 10 μm , and wherein the composition is capable of systemic delivery of a therapeutically effective amount of the drug to a mammal upon intranasal administration.

Q2
3. (Amended) A drug delivery composition according to Claim 1 or 2 wherein the microspheres comprise starch, [starch derivatives,] gelatin, albumin, collagen, or dextran [or dextran derivatives].

Q3
6. (Amended) A drug delivery composition according to Claim 1 wherein the microspheres have been [stabilised by heat treatment] treated by heating.

Please add new claims 15-28 as follows:

Q4
15. (New) The drug delivery composition of claim 1 wherein the microspheres comprise a material or ester thereof selected from the group consisting of polyvinyl alcohol, polylactide-co-glycolide, hyaluronic acid, gellan gum and pectin.

16. (New) The drug delivery composition of claim 1 wherein the microspheres comprise a material selected from the group consisting of hydroxyethyl starch, hydroxypropyl starch, carboxymethyl starch, cationic starch, acetylated starch, phosphorylated starch and grafted starch.

17. (New) A method for systemically delivering an active drug to a mammal, the method comprising:

a) providing a composition comprising a plurality of bioadhesive microspheres and an active drug, wherein at least 90 wt % of the microspheres in the composition have a diameter between 0.1 μm and 10 μm ; and

b) administering the composition to a mammal intranasally thereby to systemically delivery a therapeutically effective amount of the drug to the mammal.

18. (New) The method of claim 17 wherein the microspheres are prepared from a material that will gel in contact with the mucosal surface.

19. (New) The method of claim 17 wherein the ~~microspheres comprise a~~ ^{bioadhesive} material ^{is} selected from the group consisting of ~~starch~~, gelatin, albumin, ~~collagen and dextran~~ ^{and}.

20. (New) The method of claim 19 wherein the microspheres comprise starch.

21. (New) The method of claim 17 wherein the microsphere material is cross-linked prior to step b).

22. (New) The method of claim 17 wherein the microspheres are treated by heating prior to step b).

23. (New) The method of claim 17 the composition provided in step a) further comprises an absorption enhancer.

24. (New) The method of claim 23 wherein the absorption enhancer is a surfactant.

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10/25. (New) The method of claim 17 wherein the drug is a biologically active peptide.

11/26. (New) The method of claim 25 wherein the peptide is insulin or calcitonin.

27. (New) The method of claim 17 wherein the ~~microspheres comprise a material~~ ^{bioadhesive} ~~or ester thereof~~ selected from the group consisting of polyvinyl alcohol, polylactide-co-glycolide, hyaluronic acid, gellan gum and pectin.

28. (New) The method of claim 17 wherein the ~~microspheres comprise a material~~ ^{bioadhesive} ~~selected from the group consisting of hydroxyethyl starch, hydroxypropyl starch, carboxymethyl starch, cationic starch, acetylated starch, phosphorylated starch and grafted starch.~~ ^{is}

Remarks

Claims 1-14 are pending. Claims 1, 3 and 6 have been amended to more clearly define the compositions claimed. New claims 15-28 have been added. Support for new claims 15-17 and 27-28 is found on page 13, lines 20-30; page 5, lines 5-30; and Examples 1-3 of the specification. New claims 18-26 include limitations analogous to those of claims 2-10 as originally filed. No new matter has been introduced.

A copy of the claims as amended herein is provided in the enclosed Appendix for the Examiner's convenience.